



SphygmoCor XCEL - Traditional 510(k) Premarket Notification

510(k) Summary – SphygmoCor XCEL

In accordance with 21 CFR 807.92 the following summary of information is provided:

NOV 16 2012

Date Prepared July 13, 2012

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Classification(s)

Product Code	Classification Reference	Common/Usual Name	Class
DSK	21 C.F.R. § 870.1110	computer, blood-pressure	II
DXN	21 C.F.R. § 870.1130	System, Measurement, Blood-Pressure, Non-Invasive	II

Proprietary/Trade Name **SphygmoCor® XCEL**

Predicate Device(s)

Primary

- 1) The **SphygmoCor XCEL's Pulse Wave Analysis (PWA)** feature is substantially equivalent to primary predicate:
 - AtCor Medical Pty Ltd's **SphygmoCor CvMS System (K070795)** in technological characteristics and intended use.
- 2) The **SphygmoCor XCEL's Pulse Wave Velocity (PWV)** feature is substantially equivalent to primary predicate:
 - AtCor Medical Pty Ltd's **SphygmoCor CvMS-PWV System (K080670)** in technological characteristics and intended use.

Secondary

- 3) The **SphygmoCor XCEL's Non-Invasive Blood Pressure measurement (NIBP)** feature is substantially equivalent to secondary predicate:
 - Cheetah Medical's **Cheetah Reliant (K083093)** (SunTech Medical Advantage Mini OEM BP module incorporated in Cheetah Reliant BP Monitor)

Reason for submission **New Device**

Intended Use

The SphygmoCor® XCEL system provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a Brachial cuff.

It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

Additionally, the SphygmoCor® XCEL System automatically measures Systolic blood pressure and Diastolic blood pressure.

The SphygmoCor® XCEL Pulse Wave Velocity (PWV) option is intended to obtain PWV measurements. The PWV option is used on adult patients only.

Device Description

The SphygmoCor® XCEL System is indicated to perform non-invasive cardiovascular measurements as an adjunct to manage various cardiovascular conditions. The device can be used in any of 2 modes:

3. **Pulse Wave Analysis Measurement (PWA or CP)** – A brachial cuff is used to measure the peripheral blood pressure and arterial pulses to derive the central blood pressure waveform and corresponding parameters. The brachial blood pressure measurement is calculated using the oscillometric technique. This feature is implemented essentially by a 3rd party NIBP Module (SunTech Medical Advantage Mini OEM BP module).
4. **Pulse Wave Velocity Measurement (PWV)** – Using a non-invasive Tonometer pressure sensor and Cuff, this mode measures the time difference between the Carotid and Femoral arterial pulses measured simultaneously. To determine the carotid to femoral pulse wave velocity, the distance measured between the two arterial sites is divided by measured time difference. This Pulse Wave Velocity (PWV) is an indicator of arterial stiffness. Higher PWV's are associated with increased arterial stiffness.

The main system components include an electronics hardware module, a tonometer pressure transducer and brachial & thigh cuffs. The basic device operation involves patient's physiological signals being gathered by the electronics hardware module via the patient-contacting cuff and/or tonometer pressure sensor. These signals are then transferred via USB communications to a PC running the Microsoft Windows-based SphygmoCor XCEL Software application. This software application provides the functionality to process the physiological signals and derive the central blood pressure waveform and various other central arterial indices (including Pulse Wave Velocity). The software application also provides a GUI-based interface to allow the operator to initiate measurements and to display the measured waveforms and parameters to the operator.

Technological Characteristics Comparison

The SphygmoCor XCEL's Pulse Wave Analysis (PWA) feature is the same as the predicate SphygmoCor CvMS System (K070795) in technological characteristics and intended use, except that it uses a brachial arterial signal (captured via a brachial cuff) as compared to the radial arterial signal (captured via a tonometer) as its primary physiological input. However, the same validated General Transfer Function (GTF) methodology which derives the central pressure waveform is used in both devices. Additionally, once the central pressure waveform is derived, the same software is used to calculate all parameters.

The SphygmoCor XCEL's Pulse Wave Velocity (PWV) feature is the same as SphygmoCor CvMS-PWV System (K080670) in technological characteristics and intended use, except measurement on the new device is a single step measurement due to the simultaneous measurement of arterial signals from the carotid and femoral sites. In K080670, a 2-step measurement was required to measure the arterial signals at the carotid and femoral sites (using ECG as a timing reference). In addition, the new device uses a thigh cuff to measure the femoral arterial waveform instead of a tonometer which is used in K080670.



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The SphygmoCor XCEL's Non-Invasive Blood Pressure (NIBP) feature is the same as Cheetah Reliant (K083093) in technological characteristics and intended use. They both use the same 3rd party NIBP Module (SunTech Medical Advantage Mini OEM BP module) to measure NIBP.

Performance Data

The SphygmoCor XCEL System was designed and tested to demonstrate compliance to the following FDA consensus standards:

- Medical electrical equipment – Part 1: General requirements for safety
 - AAMI/IEC 60601-1:2005 (3rd Ed.), CSA C22.2 No 60601.1 (2008), ANSI/AAMI ES60601-1 (2005+A2)
- Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
 - AAMI/IEC 80601-2-30:2009
- Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
 - ISO 81060-2:2009
- Medical electrical equipment – Part 1: General requirements for safety Section 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests.
 - IEC 60601-1-2:2007

Biocompatibility testing clauses were not applied since all patient-contacting applied parts in the SphygmoCor XCEL system (tonometer and cuffs) have been previously cleared in predicates

System Verification and Validation testing was completed to demonstrate that the integration of the software and hardware satisfactorily met the predefined Product System Requirements. This included end-to-end testing and equivalence testing between common components of the new device and the predicates.

The software was designed and developed according to a robust software development process, and were rigorously verified and validated. Software information is provided in accordance with:

- "FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05; and
- FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.

The software verification and validation test results indicate that the SphygmoCor XCEL complies with its predetermined specification.

Finally, Side-by-Side Equivalence testing was performed for both the PWA and PWV functions of the SphygmoCor XCEL system against the identified predicates. These comparison tests demonstrated very high correlation of all measured and calculated parameters between the predicates and satisfactorily passed the acceptance criteria.

Conclusion

The indications for use, technological characteristics, and principles of operation of the SphygmoCor XCEL system are the same or similar to the predicate devices. The performance data demonstrates that the new device is as safe and effective as the predicate devices. Thus the SphygmoCor XCEL System is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 16 2012

AtCor Medical Pty. Ltd.
c/o Mr. John Abram
Manager, Regulatory Affairs and Quality Assurance
Suite 11, 1059-1063 Victoria Road
West Ryde, NSW 2114
Australia

Re: K122129
Trade/Device Names: SphygmoCor XCEL
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN, DSK
Dated: November 1, 2012
Received: November 6, 2012

Dear Mr. Abram:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

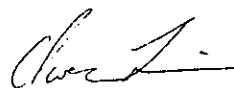
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



SphygmoCor XCEL - Traditional 510(k) Premarket Notification

Indication for Use

510(k) Number (if known): K122129

Device Name: SPHYGMOCOR XCEL SYSTEM

Indication for Use

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It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

Additionally, the SphygmoCor® XCEL System automatically measures Systolic blood pressure and Diastolic blood pressure. The SphygmoCor® XCEL Pulse Wave Velocity (PWV) option is intended to obtain PWV measurements. The PWV option is used on adult patients only.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

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Concurrence of CDRH; Office of Device Evaluation (ODE)

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